

105TH CONGRESS
2D SESSION

H. R. 3946

To establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new and revised toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness.

IN THE HOUSE OF REPRESENTATIVES

MAY 22, 1998

Mr. LANTOS (for himself, Mr. ABERCROMBIE, Mr. ACKERMAN, Mr. ANDREWS, Mr. BLUMENAUER, Mr. BONIOR, Mr. BORSKI, Mr. BROWN of California, Mr. CAMPBELL, Mr. DELAHUNT, Mr. EVANS, Mr. FARR of California, Mr. FRANK of Massachusetts, Ms. FURSE, Mr. GEJDENSON, Mr. HYDE, Mr. KLECZKA, Mr. KUCINICH, Mr. LEWIS of Georgia, Mrs. LOWEY, Mr. MANTON, Mr. MARKEY, Mr. MILLER of California, Mrs. MINK of Hawaii, Mr. MORAN of Virginia, Mr. NADLER, Mr. OBERSTAR, Ms. PELOSI, Ms. RIVERS, Mr. SCHUMER, Mr. SHAYS, Mr. TIERNEY, Mr. TOWNS, Mr. WAXMAN, Ms. WOOLSEY, Mrs. MCCARTHY of New York, and Mr. SMITH of New Jersey) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new and revised toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “ICCVAM Authoriza-
5 tion Act of 1998”.

6 **SEC. 2. INTERAGENCY COORDINATING COMMITTEE ON THE**
7 **VALIDATION OF ALTERNATIVE METHODS.**

8 (a) IN GENERAL.—The Interagency Coordinating
9 Committee on the Validation of Alternative Methods (re-
10 ferred to in this Act as “ICCVAM”) shall be sustained
11 as a permanent standing committee and continued to be
12 administered by the National Institute of Environmental
13 Health Sciences. The purposes of ICCVAM shall be to—

14 (1) increase the efficiency and effectiveness of
15 Federal agency test method review;

16 (2) eliminate duplicative efforts and share expe-
17 riences across Federal regulatory agencies;

18 (3) optimize utilization of scientific expertise
19 outside the Federal Government;

20 (4) ensure that new test methods meet the
21 needs of Federal agencies; and

22 (5) reduce, refine, and replace the use of ani-
23 mals in testing.

1 (b) COMPOSITION.—ICCVAM shall be comprised of
2 a representative from each of the following agencies and
3 organizations:

4 (1) Agency for Toxic Substances and Disease
5 Registry.

6 (2) Consumer Product Safety Commission.

7 (3) Department of Agriculture.

8 (4) Department of Defense.

9 (5) Department of Energy.

10 (6) Department of the Interior.

11 (7) Department of Transportation.

12 (8) Environmental Protection Agency.

13 (9) Food and Drug Administration.

14 (10) National Institute for Occupational Safety
15 and Health.

16 (11) National Institutes of Health.

17 (12) National Cancer Institute.

18 (13) National Institute of Environmental
19 Health Sciences.

20 (14) National Library of Medicine.

21 (15) Occupational Safety and Health Adminis-
22 tration.

23 (16) Any other agency that develops, employs,
24 or regulates the use of animals in toxicity testing.

25 (c) SCIENTIFIC ADVISORY COMMITTEE.—

1 (1) ESTABLISHMENT.—In addition, the Na-
2 tional Institute of Environmental Health Sciences
3 shall establish a Scientific Advisory Committee to
4 assist ICCVAM and the National Institute of Envi-
5 ronmental Health Sciences. The Committee shall be
6 composed of at least one knowledgeable representa-
7 tive having a history of expertise, development, or
8 evaluation in alternatives to animal toxicological
9 tests, from each of the following interests:

10 (A) The personal care, pharmaceutical, in-
11 dustrial chemicals, agriculture, and any other
12 regulated industry.

13 (B) A national animal protection organiza-
14 tion established under section 501(c)(3) of the
15 Internal Revenue Code of 1986.

16 (2) MEMBERSHIP.— The National Institute of
17 Environmental Health Sciences shall also invite to
18 be members of the Scientific Advisory Committee
19 representatives from other stakeholder organizations
20 such as:

21 (A) An academic institution.

22 (B) A State government agency.

23 (C) An international regulatory body.

1 (D) A corporation developing or marketing
2 alternative test methodologies including con-
3 tract laboratories.

4 (d) DUTIES.—ICCVAM shall carry out the following
5 duties consistent with the protection of public health and
6 the environment and for the purpose of reducing, refining,
7 and replacing the use of animals in acute and chronic toxicological tests:
8

9 (1) Review and evaluate existing and new alter-
10 native methods, including batteries of tests and test
11 screens, which may be acceptable for specific regu-
12 latory uses, including the coordination of technical
13 reviews of proposed new or revised test methods of
14 interagency interest.

15 (2) Facilitate interagency and international
16 harmonization of acute chronic toxicological test pro-
17 tocols that encourage the reduction, refinement, or
18 replacement of animal tests.

19 (3) Facilitate, promote, and provide guidance
20 on development of validation criteria and processes
21 for new methods and help promote the acceptance of
22 such methods and awareness of accepted methods by
23 Federal agencies and other stakeholders.

24 (4) File formal recommendations with each ap-
25 propriate Federal agency identifying specific agency

1 guidelines, recommendations, or regulations for each
2 new test, battery of tests, test screen, or end point
3 reviewed by ICCVAM that may be appropriate for
4 the reduction, refinement, or replacement of an ani-
5 mal test required or recommended by that Federal
6 agency for compliance with that agency's specific
7 statutes, regulations, or guidelines. Tests may be
8 recommended for a certain class of chemicals within
9 that regulatory framework.

10 (5) Consider for review and evaluation, peti-
11 tions received from the public which identify a spe-
12 cific regulation, recommendation, or guideline, and
13 which recommend alternatives and provide scientific
14 evidence of the acceptability of the alternatives for
15 the purpose of carrying out the regulatory mandate
16 in question.

17 (6) Make final recommendations to agencies
18 and responses from agencies available to the public.

19 (7) Make an annual report to be made available
20 to the public on its progress to promote the regu-
21 latory acceptance of new and revised toxicological
22 tests.

23 **SEC. 3. APPLICATION.**

24 This Act shall not apply to regulations, guidelines,
25 or recommendations related to medical research. The term

1 “medical research” means research, including research
2 performed using biotechnology, related to the causes, diag-
3 nosis, treatment, or control of physical or mental impair-
4 ments of humans or animals. The term does not include
5 the testing of a product to determine its toxicity for the
6 purpose of complying with protocols, recommendations, or
7 guidelines for testing required, recommended, or accepted
8 by a Federal regulatory agency for a product introduced
9 in commerce.

10 **SEC. 4. FEDERAL AGENCY ACTION.**

11 (a) IDENTIFICATION OF TESTS.—Within 180 days
12 after the date of enactment of this Act, each Federal agen-
13 cy authorized to carry out a regulatory program which re-
14 quires or recommends acute or chronic toxicological test-
15 ing shall identify any regulation or industry-wide guideline
16 which specifically, or in practice requires, recommends, or
17 encourages the use of an animal acute or chronic tox-
18 iological test and shall forward to ICCVAM a list of these
19 regulations, guidelines, and recommendations along with
20 the test or tests recommended or required.

21 (b) ALTERNATIVES.—Each Federal agency shall pro-
22 mote and encourage the development and use of alter-
23 natives to animal tests, including batteries of tests and
24 test screens, where appropriate, for the purpose of comply-
25 ing with Federal regulations, guidelines, or recommenda-

1 tions, in each instance, and for each chemical class, for
2 which such tests are found to be effective for generating
3 data at least equivalent for hazard identification or dose-
4 response assessment purposes to the method established
5 under the current regulatory scheme.

6 (c) TEST VALIDATION.—Each Federal agency shall
7 ensure that any new acute or chronic toxicity test, includ-
8 ing animal tests and alternatives, is determined to be valid
9 for its proposed use prior to requiring, recommending, or
10 encouraging its application.

11 (d) REVIEWS.—Each Federal agency shall review any
12 formal recommendations from ICCVAM to promulgate
13 new regulations or draft new guidelines or recommenda-
14 tions to promote the ICCVAM recommendations and no-
15 tify ICCVAM in writing of its findings within 180 days
16 of receipt of the recommendations.

17 (e) RECOMMENDATION ADOPTION.—Each Federal
18 agency shall adopt the ICCVAM recommendations unless
19 it determines that—

20 (1) the alternative is not adequate in terms of
21 biological relevance for the regulatory goal author-
22 ized by the agency;

23 (2) the alternative does not generate data at
24 least equivalent for the appropriate hazard identi-

1 fication or dose-response assessment purpose as the
2 method recommended by the agency;

3 (3) the agency does not employ, recommend, or
4 require testing for that class of chemical or for the
5 recommended end point; or

6 (4) each government agency retains fully the
7 prerogative of deciding whether the new test method
8 is acceptable for satisfactorily fulfilling the test
9 needs for their particular agency and its respective
10 congressional mandate.

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